

REMARKS

The present application relates to inbred maize plant and seed PH48V. Claims 1-10 are pending in the present application. No new matter has been added by way of amendment. Applicant respectfully requests consideration of the claims in view of the following remarks.

Detailed Action

Applicant acknowledges that copies of the PTOL-1449 and 892 forms from the parent application Serial No. 09/490,666, now U.S. Patent No. 6,734,348 have been received. The Examiner has requested a supplemental Information Disclosure Statement (IDS) citing those references previously cited on the 892 forms in the parent application. Applicant has enclosed herewith the requested supplemental IDS form.

Double Patenting

The Examiner rejects claims 1-6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of copending U.S. Patent No. 6,734,348. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the method of producing an F1 hybrid with PH48V as one of the parents as claimed by the patent, to obtain the resultant F1 hybrid as instantly claimed.

Applicant is herein submitting a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c), which disclaims any term of a patent issuing from this application which would extend beyond the term of copending U.S. Patent No. 6,734,348. Therefore, Applicant submits that the claims are in proper form for allowance and respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection.

Rejections Under 35 U.S.C. § 112, First Paragraph

A. Written description regarding Claims 1-10

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The Examiner states the "claims are broadly drawn to any F1 hybrid produced by crossing a single inbred parent PH48V with any of a multitude of unspecified second parents, wherein half of the genetic composition of the hybrid is contributed by the first inbred parent. Claims 7-10 are drawn to F1 hybrid plants which somehow contain an intact cell from an inbred parent". The Examiner further states "the specification only provided guidance for the traits exhibited by the single inbred parent PH48V, and for traits exhibited by crossing a single inbred parent PH48V with one other inbred parents (see Tables 4A-4E). No guidance is provided regarding the genetic composition of PH48V at any locus or on any chromosome. No guidance is provided regarding the genetic composition of any of a multitude of non-exemplified inbreds or hybrids at any single locus or on any chromosome. Furthermore, no guidance is provided for the obtention or characterization of a hybrid plant which somehow contains an intact cell from an inbred parent". (Office Action, p. 3).

Applicant respectfully traverses this rejection. Applicant submits that the genus of F1 hybrids encompassed by Applicant's claims 1-10 are described in relation to the deposit which would provide to one of skill in the art the ability to determine the cells and/or chromosomes of inbred line PH48V, which provide an identifying structural feature possessed by all members of the claimed genus.

Exhibit 1, submitted herewith, is a visual representation of the fact that most of the cells in a corn inbred will have two essentially duplicate sets of ten chromosomes. (For illustrative purposes the ten chromosomes are represented by three rectangles in the Exhibits).

When the inbred is used to produce an F1 hybrid, the inbred will produce a haploid cell, such as pollen or an ovule. These haploid cells will receive one of the inbred's sets of chromosomes.

As known to one of ordinary skill in the art and as shown in Exhibits 2 and 3, attached herewith, when F1 hybrid seed is produced it will receive one complete set of chromosomes from the inbred parent, regardless of whether the inbred is used as the male or female parent of the F1 hybrid. Therefore, the genus of F1 hybrid seed and plants encompassed by Applicant's claims 1-10 all share the common structural attribute of having a complete set of the unique chromosomes of PH48V. Stated in patent terms, it can be said that an F1 hybrid made with PH48V *comprises* the unique chromosomes of inbred PH48V. This unique set of chromosomes can be characterized by molecular marker methods known to those of ordinary skill in the art.

This set of chromosomes disclosed in the present application via the seed of inbred line PH48V deposited by Applicant at the ATCC. Further, this unique set of chromosomes can be characterized by molecular marker methods known to those of ordinary skill in the art. Therefore, while the Examiner has stated Applicant has not provided guidance, Applicant has provided guidance as to identifying characteristics of the genetic composition of the entire genus of hybrids claimed.

According to *Enzo*, the deposit of a material in a public depository is an adequate description of that material for purposes of the written description requirement. *Enzo Biochem, Inc.*, 296 F.3d at 1325, 63 U.S.P.Q.2d at 1613. In addition, *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406, teaches that claims may satisfy the written description requirement where they disclose "structural features commonly possessed by members of the genus that distinguish them from others." The unique set of chromosomes of inbred maize line PH48V is an identifying structural characteristic present in Applicant's seed deposit of PH48V. The SSR profile of PH48V is obtainable from the deposit by one of ordinary skill in the art.

Further, Applicant has also provided data (*see* Table 3, specification p. 42, and Tables 4A-4E, specification p. 43-49) that demonstrate the results of hybrid combination of PH48V. Applicant has provided actual descriptions of F1 hybrids produced with PH48V in the application as filed. Applicant performed evaluations on the hybrid progenies of PH48V and provided the results of such evaluation in Tables 3 and 4. The results of these evaluations show that PH48V is useful in many different F1 hybrid combinations.

For example, see Table 3, titled "Average Inbred by Tester Performance Comparing PH48V to PH07D Crossed to the Same Inbred Testers and Grown in the Same Experiments" on page 42 of the specification. As the title explains, inbred lines PH48V to PH07D were both crossed to a large number of common inbreds (ones that were not PH48V to PH07D) and the results of these crosses were evaluated and reported in this table.

Table 3 demonstrates that PH48V, at the time that the application was filed, had been crossed to different inbred lines in order to produce different F1 hybrid varieties. The table also shows the average scores of those different F1 hybrid varieties for the 16 different traits listed. This data demonstrates that inbred PH48V performs well in a variety of F1 hybrid crosses, a characteristic referred to by corn breeders as good general combining ability.

In addition, Table 3 shows similar results for PH07D, a line that is not the subject of this application. The data was provided for PH07D because such data may be used by a breeder to compare the general combining ability of PH48V with the general combining ability of PH07D. This combining ability data can be viewed as a trait of the inbred, and is useful data when comparing two inbred lines. This table clearly demonstrates the ability of PH48V to perform well in a broad genus of F1 hybrids.

In addition to the general combining ability of PH48V as described in Table 3, Applicant has also provided data in Tables 4A-4E that compare a specific F1 hybrid produced from the cross of inbred PH48V and inbred PH0KT with other F1 hybrids. (Specification, p. 43-49). This data demonstrates the good specific combining ability of inbred PH48V. As evidenced by the data, the F1 hybrid exhibits the characteristics of high yield, above average resistance to stalk lodging, above average resistance to root lodging, strong staygreen, tall plant, high ear placement and strong disease resistance. (See specification, p. 15, lines 25-28).

According to the MPEP, § 2163(II)(A)(3)(a)(ii), the written description requirement for a genus may be satisfied by sufficiently describing a representative number of species actually reduced to practice. Applicant has provided data in Tables 3 and 4 for F1 hybrid combinations made with PH48V whose F1 hybrid seed and plants were reduced to practice as of the filing date. Accordingly, the Applicant has satisfied the written description requirement for claims 1-10.

The Examiner states "[c]laims 7-10 are drawn to F1 hybrid plants which somehow contain an intact cell from an inbred parent". (Office Action, p. 3). One of ordinary skill in the art would know that the pericarp tissue is genetically identical to the maternal parent. It is well known to one of skill in the art that a maize seed is comprised of various types of tissue with different genetic composition. The pericarp tissue that surrounds the seed is 2n maternal tissue only, the embryo is 2n tissue resulting from the fusion of one maternal and one paternal gamete, and the endosperm is 3n tissue resulting from the fusion of two maternal and one paternal gametes. The seed of maize has been described as a 'one-seeded fruit', where the ovary wall from the maternal parent is transformed into the tough outer pericarp that surrounds the kernel. Therefore, Applicant points out that intact cells from inbred PH48V will be a component of the F1 hybrid seed produced with PH48V as the maternal parent. Further, the genetic composition of the pericarp tissue of the F1 hybrid seed is an identifying structural feature present in the

plants produced from the deposited seed of PH48V and can be characterized by molecular markers.

As stated above, the essential test of written description is whether Applicant has demonstrated possession of a claimed invention such that one skilled in the relevant art would recognize that the Applicant was the inventors of the invention as claimed. Applicant has taught that the main utility of an inbred line is to produce F1 hybrid seed and plants. (*See* specification, p.14, lines 17-18). As the Examiner has acknowledged, Applicant has provided guidance for the traits exhibited by crossing the inbred parent PH48V with another inbred parent thereby producing an actual F1 hybrid seed and plant. Applicant has made a deposit of inbred PH48V that fully enables others to make the genus of F1 hybrid seed and plants of claims 1-10. One skilled in the art would thus recognize that Applicant was in possession of F1 hybrid seed and plants produced from line PH48V as of the filing date of the application.

B. Enablement regarding Claims 1-10

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states the "claims are broadly drawn to any F1 hybrid produced by crossing a single inbred parent PH48V with any of a multitude of unspecified second parents, wherein half of the genetic composition of the hybrid is contributed by the first inbred parent. (Office Action, p. 5).

The Examiner states that Kevern, U.S. Patent No. 5,850,009 suggests "[t]he use of *breeding crosses* to obtain particular desirable corn individual possessing a particular genetic and morphological complement of traits is unpredictable, due to the large number of genes involved, and the interaction of these genes with selection methods, environmental effects, breeder actions." (*See* Kevern, column 4, lines 37-46, emphasis added). (Office Action, p. 6).

Applicant respectfully traverses. The Examiner refers to a section of Kevern (column 4, lines 37-46) that is specifically discussing segregating populations of seed. A segregating population is not the invention claimed in claims 1-10. An F1 hybrid of the claimed invention is not a segregating population as assumed by the Examiner. Rather, the F1 hybrids of the present

application are based on stable inbred lines where the genetics are of a fixed nature and whereby the hybrid receives the genetics of the inbred line PH48V. Kevern states:

"Maize is an important and valuable field crop. Thus a continuing goal of plant breeders is to develop high-yielding maize hybrids that are agronomically sound based on stable inbred lines. The reasons for this goal are obvious: to maximize the amount of grain produced with the inputs used and minimize susceptibility of the crop to pests and environmental stresses. To accomplish this goal, the maize breeder must select and develop superior inbred parental lines for producing hybrids" (column 4, lines 23-31).

Applicant asserts that in order to accomplish the goal of developing maize hybrids it is necessary to identify genetically unique and stable inbred lines, such as the claimed invention, in order to produce the F1 hybrid seed. It is vital to conceptually understand that the cited section of Kevern by the Examiner is not describing the use of stable inbred lines to produce F1 hybrid seed. An F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it, which genetics will be present in both the inbred and the F1 hybrid. In contrast, Kevern is describing the development of a genetically segregating population which is distinct from genetically stable F1 hybrid seed. Therefore, Applicant respectfully states the Examiner has misinterpreted the claimed invention and inappropriately applied Kevern to the present invention. The use of stable inbred lines, such as PH48V, does allow for one of ordinary skill in the art to make F1 hybrids produced from inbred line PH48V.

The Examiner also cites Carlone, U.S. Patent No. 5,763,755 stating that "the usefulness of a multitude of hybrids produced by crossing a single inbred with a multitude of non-exemplified breeding partners is unpredictable, given the polygenic nature of inheritance of many agronomic traits, the difficult of predicting the expression of said traits in hybrid progeny of inbreds which do not express them, and the failure of those collections of traits to be transmitted to progeny of parents containing them (see e.g., Carlone, columns 1-2)". (Office Action, p. 6).

Applicant traverses this argument. The Examiner cites Carlone which states:

"Maize breeders select for a variety of traits in inbreds that impact hybrid performance along with selecting for acceptable parental traits. Such traits included yield potential in hybrid combination; dry down; grain moisture at harvest; greensnap; resistance to root lodging; resistance to stalk lodging; grain quality; disease and insect resistance; ear and plant height; performance in different soil types such as: low level of organic matter, clay, sand, black, high pH, low pH; performance in: wet environments, drought environments, and no

tillage conditions. These traits appear to be governed by a complex genetic system that makes selection and breeding of an inbred line extremely difficult. Even if an inbred in hybrid combination has excellent yield (a desired characteristic), it [the inbred] may not be useful because it fails to have acceptable parental traits such as seed yield, seed size, pollen production, good silks, plant height, etc." (Carlone, paragraph bridging columns 1 and 2, language in [] added by Applicant for clarification).

Carlone is discussing the traits of the inbred (or parental) line and their development. The referenced section of Carlone is specifically discussing selection within the segregating populations of seed that a breeder uses for inbred development. An F1 hybrid of the claimed invention is not a segregating population as assumed by the Examiner. Further, the patent cited by the Examiner is one in which Carlone developed a novel inbred line and sought and was allowed claims to the hybrid seed and plants produced from the novel inbred line. Therefore, Applicant respectfully states the Examiner has misinterpreted the cited portion of the Carlone reference and has inappropriately applied Carlone to the present invention. The use of stable inbred lines, such as PH48V, does enable one of ordinary skill in the art to create hybrids comprising the disclosed chromosomes of PH48V.

The Examiner goes on to cite Stuber *et al.* stating that the cited reference teaches that "grain yield and ear number were strongly affected by environmental influences such as plant density, and that epistatic genetic interactions prevented accurate performance prediction of particular hybrids derived from particular crosses (see, e.g., page 503, Abstract; page 505, column 1, first and third full paragraphs; page 506, paragraph bridging the columns)". (Office Action, p. 6).

Applicant traverses this argument. Applicant asserts that Stuber *et al.* is comparing synthetic populations and not F1 hybrids as taught by the present application. (See Stuber *et al.*, p. 503 under *Materials and Methods*, where Stuber notes that all possible crosses, including 3-way and double crosses, were made). In contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. An F1 hybrid as claimed is not a genetically mixed population, but rather is highly homogeneous and reproducible because it is made from the highly homogeneous and reproducible inbred maize line PH48V. (Specification, p. 14, lines 17-18). Thus, Applicant respectfully states the arguments set forth by the Examiner do not apply to the presently claimed invention.

The Examiner also references Melchinger *et al.* stating that the reference teaches "that epistatic effects reduced the amount of heterosis in hybrid crosses" (see, e.g., page 231 column 1, bottom paragraph; column 2, first paragraph of Introduction; page 223, column 2, bottom paragraph; page 237, column 1, top paragraph). (Office Action, p. 6).

Applicant traverses this argument. As discussed *supra* with respect to Stuber *et al.*, Applicant asserts that Melchinger *et al.* is discussing the making of all possible crosses including F2, 3-way and backcrosses, to produce a population of seed (Melchinger, first sentence of Summary). In contrast, the claimed invention teaches the use of a stable and reproducible inbred line to produce a stable and reproducible F1 hybrid. Thus, Applicant respectfully asserts the arguments set forth by the Examiner do not apply to the presently claimed invention.

In addition, it is important to note that the claimed F1 hybrid seed is routinely and easily produced by crossing a plant from an inbred maize line PH48V with a plant from another inbred maize line. Applicant has made a deposit of inbred PH48V that fully enables others to obtain the inbred seed needed to make the claimed F1 hybrids.

The Examiner also goes on to state that "[t]he plant resulting from the diploid embryo may contain genetic material from both parents, but does not contain any intact egg or sperm cell (or any other type of cell) from the inbred parents". (Office Action, p. 7).

Applicant reiterates that a maize seed is comprised of various components, such as pericarp, embryo and endosperm. The origin of the gametes is not simply the result of fusion of a haploid sperm (pollen) and haploid egg (ovule) to form a diploid embryo. As explained previously, the pericarp tissue is genetically identical to the maternal parent. Thus, one would produce the claimed F1 hybrid by using inbred PH48V as a maternal parent.

Accordingly, Applicant submits that claims 1-10 are fully enabled. In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Summary

35 U.S.C. § 112, first paragraph - Written Description and Enablement regarding Claims 1-10

Applicant submits there has been adequate written description and a reduction to practice of the claimed F1 hybrid genus. The genus of F1 hybrids encompassed by Applicant's claims 1-10 are described in relation to the cells and/or chromosomes of inbred line PH48V, which

provide an identifying structural feature possessed by all members of the claimed genus. Specifically, the genus of F1 hybrid seed and plants encompassed by Applicant's claims all share the common structural attribute of having a complete set of the chromosomes of PH48V. In addition, the SSR profile of PH48V is obtainable from the deposit of PH48V by one of ordinary skill in the art, utilizing SSR markers publicly known at the time of filing this application. In addition, the F1 hybrid seed also will comprise an intact cell from inbred maize line PH48V when PH48V is the maternal parent. Therefore, one of ordinary skill in the art would thus recognize that Applicant was in possession of F1 hybrid maize seed and plants produced from PH48V. Applicant respectfully submits that claims 1-10 are adequately described.

Applicant also respectfully asserts that the claimed invention is enabled by the present application. The claimed F1 hybrid seed is produced by crossing a plant from inbred maize line PH48V with a plant from another inbred maize line whereby the F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it. Seed of inbred line PH48V has been deposited and it is well known to one skilled in the art how to use PH48V to produce F1 hybrid seed. Applicant has created a novel maize inbred line PH48V, and by virtue of the deposit of PH48V, one of ordinary skill in the art is fully enabled to produce inbred maize line PH48V and F1 hybrid seed and plants produced from PH48V. It is respectfully submitted that Applicant has described and enabled the production of the F1 hybrid seed and plants produced with PH48V, and are entitled to the scope of their invention as claimed.

Applicant further acknowledges that the claims (1-10) are deemed free of the prior art. The Examiner further states the prior art fails to teach or suggest inbred maize plant PH48V, or methods of using it.

Conclusion

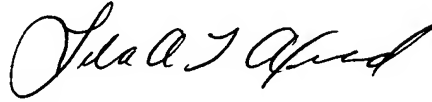
In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Please consider this a one month extension of time from March 23, 2005 to April 23, 2005, under the provision of 37 C.F.R. § 1.136(a) and charge Deposit Account No. 26-0084 for the amount of \$120.00. No other fees or extensions of time are believed to be due in connection

with this amendment; however, consider this a request for any fees inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Lila A. T. Akrad".

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